Internet through any of the methods provided under paragraph (b)(1) of this section, you may register by CD–ROM.

(i) Registrants submitting their registrations in CD–ROM format must use ISO 9660 (CD–R or CD–RW) data format.

(ii) These files must be submitted on a portable document format (PDF) rendition of the registration form (FDA Form No. 3733) and be accompanied by one signed copy of the certification statement that appears on the registration form.

(iii) Each submission on the CD–ROM must contain the same preferred mailing address in the appropriate block on FDA Form No. 3733.

(iv) A CD–ROM may contain registrations for as many facilities as needed up to the CD–ROM's capacity.

(v) The registration on the CD–ROM for each separate facility must have a unique file name up to 32 characters long, the first part of which may be used to identify the parent company.

(vi) You must mail the CD–ROM to the U.S. Food and Drug Administration, 5600 Fishers Lane (HFS–681), Rockville, MD 20857.

(vii) If FDA receives a CD–ROM that does not comply with these specifications, it will return the CD–ROM to the submitter unprocessed.

(viii) FDA will enter CD–ROM submissions that comply with these specifications into its registration system, along with the complete and legible mailed and faxed submissions, as soon as practicable, in the order FDA receives them.

(ix) For each facility on the CD–ROM, FDA will mail to the preferred mailing address a copy of the registration(s) as entered, confirmation of registration, and each facility's assigned registration number.

(x) If any information you previously submitted was incorrect at the time of submission, you must immediately update your facility's registration. If any information you previously submitted that was correct at the time of submission subsequently changes, you must update your facility's registration within 60 calendar days.

(xi) Your facility is considered registered once FDA enters your facility's registration data into the registration system and the system generates a registration number.

(c) No registration fee is required.

(d) You must submit all registration information in the English language. All information must be submitted using the Latin (Roman) alphabet.

(e) Each registrant must submit the following information through one of the methods described in paragraph (b) of this section:

(1) The name, full address, and phone number of the farm; and

(2) The average or usual number of layers of each house and number of poultry houses on the farm.

(3) A statement in which the shell egg producer certifies that the information submitted is true and accurate. If the individual submitting the form is not the shell egg producer in charge of the farm, the registration must also include a statement in which the individual certifies that the information submitted is true and accurate, certifies that he/she is authorized to submit registration, and identifies by name, address, and telephone number, the individual who authorized submission of the registration. Each registration must include the name of the individual registering the farm submitting the registration, and the individual's signature (for paper and CD–ROM options).

(f) Registered egg producers must submit an update to a registration within 60-calendar days of any change to any of the information previously submitted by any of the means as provided in § 118.11(b).

(g) Registered egg producers must notify FDA within 120 days of ceasing egg production by completing sections 1b, 1c, and 2 of Form 3733. This notification is not required if you are a seasonal egg producer or you temporarily cease operation due to labor disputes, fire, natural disasters, or other temporary conditions.

[74 FR 33095, July 9, 2009, as amended at 75 FR 18751, Apr. 13, 2010]

§ 118.12 Enforcement and compliance.

(a) *Authority*. This part is established under authority of the Public Health Service Act (the PHS Act). Under the FFDCA, the Food and Drug Administration (FDA) can enforce the food

adulteration provisions under 21 U.S.C. 331 through 334 and 342. Under the PHS Act (42 U.S.C. 264), FDA has the authority to make and enforce regulations for the control of communicable diseases. FDA has established the following administrative enforcement procedures for the diversion or destruction of shell eggs and for informal hearings under the PHS Act:

(1) Upon a finding that any shell eggs have been produced or held in violation of this part, an authorized FDA representative or a State or local representative in accordance with paragraph (c) of this section may order such eggs to be diverted, under the supervision of said representative, for processing in accordance with the Egg Products Inspection Act (EPIA) (21 U.S.C. 1031 *et seq.*) or by a treatment that achieves at least a 5-log destruction of SE or destroyed by or under the supervision of an officer or employee of FDA, or, if applicable, of the State or locality in accordance with the following procedures:

(i) *Order for diversion or destruction under the PHS Act.* Any district office of FDA or any State or locality acting under paragraph (c) of this section, upon finding shell eggs that have been produced or held in violation of this regulation, may serve a written order upon the person in whose possession the eggs are found requiring that the eggs be diverted, under the supervision of an officer or employee of the issuing entity, for processing in accordance with the EPIA (21 U.S.C. 1031 *et seq.*) or by a treatment that achieves at least a 5-log destruction of SE or destroyed by or under the supervision of the issuing entity, within 10-working days from the date of receipt of the order, unless, under paragraph (a)(2)(iii) of this section, a hearing is held, in which case the eggs must be diverted or destroyed consistent with the decision of the Regional Food and Drug Director under paragraph (a)(2)(v) of this section. The order must include the following information:

(A) A statement that the shell eggs identified in the order are subject to diversion for processing in accordance with the EPIA or by a treatment that achieves at least a 5-log destruction of SE or destruction;

(B) A detailed description of the facts that justify the issuance of the order;

(C) The location of the eggs;

(D) A statement that these eggs must not be sold, distributed, or otherwise disposed of or moved except as provided in paragraph (a)(1)(iv) of this section;

(E) Identification or description of the eggs;

(F) The order number;

(G) The date of the order;

(H) The text of this entire section;

(I) A statement that the order may be appealed by written appeal or by requesting an informal hearing;

(J) The name and phone number of the person issuing the order; and

(K) The location and telephone number of the office or agency issuing the order and the name of its Director.

(ii) *Approval of District Director.* An order, before issuance, must be approved by FDA's District Director or the Acting District Director. If prior written approval is not feasible, prior oral approval must be obtained and confirmed by written memorandum as soon as possible.

(iii) *Labeling or marking of shell eggs under order.* An FDA, State, or local representative issuing an order under paragraph (a)(1)(i) of this section must label or mark the shell eggs with official tags that include the following information:

(A) A statement that the shell eggs are detained in accordance with regulations issued under section 361(a) of the PHS Act (42 U.S.C. 264(a)).

(B) A statement that the shell eggs must not be sold, distributed or otherwise disposed of or moved except, after notifying the issuing entity in writing, to:

(*1*) Divert them for processing in accordance with the EPIA or by a treatment that achieves at least a 5-log destruction of SE or destroy them or

(*2*) Move them to another location for holding pending appeal.

(C) A statement that the violation of the order or the removal or alteration of the tag is punishable by fine or imprisonment or both (section 368 of the PHS Act (42 U.S.C. 271)).

(D) The order number and the date of the order, and the name of the government representative who issued the order.

(iv) *Sale or other disposition of shell eggs under order.* After service of the order, the person in possession of the shell eggs that are the subject of the order must not sell, distribute, or otherwise dispose of or move any eggs subject to the order unless and until receiving a notice that the order is withdrawn after an appeal except, after notifying FDA's district office or, if applicable, the State or local representative, in writing, to:

(A) Divert or destroy them as specified in paragraph (a)(1)(i) of this section, or

(B) Move them to another location for holding pending appeal.

(2) The person on whom the order for diversion or destruction is served may either comply with the order or appeal the order to the Regional Food and Drug Director in accordance with the following procedures:

(i) *Appeal of a detention order.* Any appeal must be submitted in writing to FDA's District Director in whose district the shell eggs are located within 5-working days of the issuance of the order. If the appeal includes a request for an informal hearing, the hearing must be held within 5-working days after the appeal is filed or, if requested by the appellant, at a later date, which must not be later than 20-calendar days after the issuance of the order. The order may also be appealed within the same period of 5-working days by any other person having an ownership or proprietary interest in such shell eggs. The appellant of an order must state the ownership or proprietary interest the appellant has in the shell eggs.

(ii) *Summary decision.* A request for a hearing may be denied, in whole or in part and at any time after a request for a hearing has been submitted, if the Regional Food and Drug Director or his or her designee determines that no genuine and substantial issue of fact has been raised by the material submitted in connection with the hearing or from matters officially noticed. If the Regional Food and Drug Director determines that a hearing is not justified, written notice of the determination will be given to the parties explaining the reason for denial.

(iii) *Informal hearing.* Appearance by any appellant at the hearing may be by mail or in person, with or without counsel. The informal hearing must be conducted by the Regional Food and Drug Director or his designee, and a written summary of the proceedings must be prepared by the Regional Food and Drug Director.

(A) The Regional Food and Drug Director may direct that the hearing be conducted in any suitable manner permitted by law and by this section. The Regional Food and Drug Director has the power to take such actions and make such rulings as are necessary or appropriate to maintain order and to conduct an informal, fair, expeditious, and impartial hearing, and to enforce the requirements concerning the conduct of hearings.

(B) Employees of FDA will first give a full and complete statement of the action that is the subject of the hearing, together with the information and reasons supporting it, and may present oral or written information relevant to the hearing. The party requesting the hearing may then present oral or written information relevant to the hearing. All parties may conduct reasonable examination of any person (except for the presiding officer and counsel for the parties) who makes any statement on the matter at the hearing.

(C) The hearing shall be informal in nature, and the rules of evidence do not apply. No motions or objections relating to the admissibility of information and views will be made or considered, but any party may comment upon or rebut any information and views presented by another party.

(D) The party requesting the hearing may have the hearing transcribed, at the party's expense, in which case a copy of the transcript is to be furnished to FDA. Any transcript of the hearing will be included with the Regional Food and Drug Director's report of the hearing.

(E) The Regional Food and Drug Director must prepare a written report of the hearing. All written material presented at the hearing will be attached to the report. Whenever time permits, the Regional Food and Drug Director

may give the parties the opportunity to review and comment on the report of the hearing.

(F) The Regional Food and Drug Director must include as part of the report of the hearing a finding on the credibility of witnesses (other than expert witnesses) whenever credibility is a material issue, and must include a recommended decision, with a statement of reasons.

(iv) *Written appeal.* If the appellant appeals the detention order but does not request a hearing, the Regional Food and Drug Director must render a decision on the appeal affirming or revoking the detention order within 5-working days after the receipt of the appeal.

(v) *Regional Food and Drug Director decision.* If, based on the evidence presented at the hearing or by the appellant in a written appeal, the Regional Food and Drug Director finds that the shell eggs were produced or held in violation of this section, he must affirm the order that they be diverted, under the supervision of an officer or employee of FDA for processing under the EPIA or by a treatment that achieves at least a 5-log destruction of SE or destroyed by or under the supervision of an officer or employee of FDA; otherwise, the Regional Food and Drug Director must issue a written notice that the prior order is withdrawn. If the Regional Food and Drug Director affirms the order, he must order that the diversion or destruction be accomplished within 10-working days from the date of the issuance of his decision. The Regional Food and Drug Director's decision must be accompanied by a statement of the reasons for the decision. The decision of the Regional Food and Drug Director constitutes final agency action, subject to judicial review.

(vi) *No appeal.* If there is no appeal of the order and the person in possession of the shell eggs that are subject to the order fails to divert or destroy them within 10-working days, or if the demand is affirmed by the Regional Food and Drug Director after an appeal and the person in possession of such eggs fails to divert or destroy them within 10-working days, FDA's district office or, if applicable, the State or local representative may designate an officer or employee to divert or destroy such eggs. It shall be unlawful to prevent or to attempt to prevent such diversion or destruction of the shell eggs by the designated officer or employee.

(b) *Inspection.* Persons engaged in production of shell eggs must permit authorized representatives of FDA to make, at any reasonable time, an inspection of the egg production establishment in which shell eggs are being produced. Such inspection includes the inspection and sampling of shell eggs and the environment, the equipment related to production of shell eggs, the equipment in which shell eggs are held, and examination and copying of any records relating to such equipment or eggs, as may be necessary in the judgment of such representatives to determine compliance with the provisions of this section. Inspections may be made with or without notice and will ordinarily be made during regular business hours.

(c) *State and local cooperation.* Under sections 311 and 361 of the Public Health Service Act, any State or locality that is willing and able to assist the agency in the enforcement of §§ 118.4 through 118.10, and is authorized to inspect or regulate egg production establishments, may, in its own jurisdiction, enforce §§ 118.4 through 118.10 through inspections under paragraph (b) of this section and through administrative enforcement remedies specified in paragraph (a) of this section unless FDA notifies the State or locality in writing that such assistance is no longer needed. A state or locality may substitute, where necessary, appropriate State or local officials for designated FDA officials in this section. When providing assistance under paragraph (a) of this section, a State or locality may follow the hearing procedures set out in paragraphs (a)(2)(iii) through (a)(2)(v) of this section, or may utilize comparable State or local hearing procedures if such procedures satisfy due process.

(d) *Preemption.* No State or local governing entity shall establish, or continue in effect any law, rule, regulation, or other requirement regarding prevention of SE in shell eggs during production, storage, or transportation

that is less stringent than those required by this part.

PART 119—DIETARY SUPPLEMENTS THAT PRESENT A SIGNIFICANT OR UNREASONABLE RISK

AUTHORITY: 21 U.S.C. 321, 342, 343, 371.

§ 119.1 Dietary supplements containing ephedrine alkaloids.

Dietary supplements containing ephedrine alkaloids present an unreasonable risk of illness or injury under conditions of use recommended or suggested in the labeling, or if no conditions of use are recommended or suggested in the labeling, under ordinary conditions of use. Therefore, dietary supplements containing ephedrine alkaloids are adulterated under section 402(f)(1)(A) of the Federal Food, Drug, and Cosmetic Act.

[69 FR 6853, Feb. 11, 2004]

PART 120—HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) SYSTEMS

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AUTHORITY: 21 U.S.C. 321, 342, 343, 346, 348, 371, 374, 379e, 381, 393; 42 U.S.C. 241, 242l, 264.

SOURCE: 66 FR 6197, Jan. 19, 2001, unless otherwise noted.

Subpart A—General Provisions

§ 120.1 Applicability.

(a) Any juice sold as such or used as an ingredient in beverages shall be processed in accordance with the requirements of this part. Juice means the aqueous liquid expressed or extracted from one or more fruits or vegetables, purees of the edible portions of one or more fruits or vegetables, or any concentrates of such liquid or puree. The requirements of this part shall apply to any juice regardless of whether the juice, or any of its ingredients, is or has been shipped in interstate commerce (as defined in section 201(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 321(b)). Raw agricultural ingredients of juice are not subject to the requirements of this part. Processors should apply existing agency guidance to minimize microbial food safety hazards for fresh fruits and vegetables in handling raw agricultural products.

(b) The regulations in this part shall be effective January 22, 2002. However, by its terms, this part is not binding on small and very small businesses until the dates listed in paragraphs (b)(1) and (b)(2) of this section.

(1) For small businesses employing fewer than 500 persons the regulations in this part are binding on January 21, 2003.

(2) For very small businesses that have either total annual sales of less than $500,000, or if their total annual sales are greater than $500,000 but their total food sales are less than $50,000; or the person claiming this exemption employed fewer than an average of 100 full-time equivalent employees and fewer than 100,000 units of juice were sold in the United States, the regulations are binding on January 20, 2004.

§ 120.3 Definitions.

The definitions of terms in section 201 of the Federal Food, Drug, and Cosmetic Act, § 101.9(j)(18)(vi) of this chapter, and parts 110 and 117 of this chapter are applicable to such terms when used in this part, except that the definitions and terms in parts 110 and 117 do not govern such terms where such terms are redefined in this part and except that the terms facility, hazard,